THIN-FILM PERIPHERAL NERVE ELECTRODE

Tri-Annual Progress Report

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by

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1.0 BACKGROUND

A program to develop a functional neuromuscular system (FNS) capable of graded and stable activation of hand muscles for the restoration of grasp in quadriplegic individuals is being undertaken. The objective of the program is the development of a thin film neural cuff electrode and the demonstration of the efficacy of the electrode for grasp in an *in vivo* study using a raccoon model.

Specific features of the proposed electrode include:

- multiple, independently addressable charge injection sites that will facilitate implementation of established and emerging stimulation protocols such as anodal field steering and anodal blocking;
- leads and electrodes are vacuum deposited on a planar, monolithic fluorocarbon substrate that is flexible and avoids bulky interconnects in close proximity to the implantation site;
- charge injection electrodes of Pt or activated iridium oxide (AIROF), both of which are stable under the anticipated charge injection protocols;
- fluorocarbon substrates that can be thermoformed into a self-sizing cuff to allow a snug but elastic fit to the nerve.

The circumneural electrodes are fabricated by vacuum depositing metal films on thin sheets of fluorocarbon polymer and photolithographically patterning and the leads and charge injection sites. The patterned substrate is then thermally sealed with a second polymer layer to electronically isolate the leads from the physiological environment. The charge injection sites are exposed by a combination of photolithography and ion or plasma etching of vias through the polymer overlayer. Once all planar fabrication processes, i.e., photolithography, vacuum deposition, and etching have been completed, the electrode is cut out of the substrate and the desired cuff and lead geometries created by thermoforming.

An example of an electrode in planar geometry prior to thermoforming the cuff is shown in Figure 1. The leads and charge injection sites are patterned on a large polymer substrate with the leads extending to a bonding pad located several centimeters from the cuff. Four charge injection sites, designed to evaluate anodal steering, are shown on the cuff.

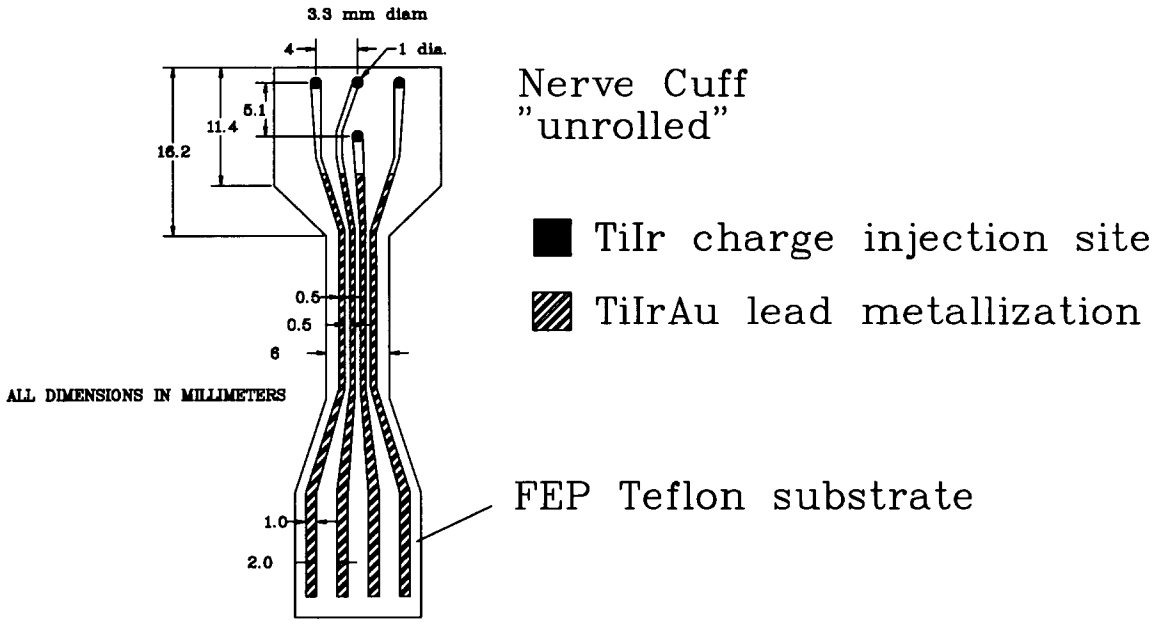

Figure 1. A circumneural cuff having four charge injection sites in a geometry suitable for evaluating anodal steering.

2.0 TECHNICAL PROGRESS

In the third reporting period, emphasis has been placed on refining experimental procedures for the animal studies with particular attention to obtaining valid EMG recordings during stimulation. Electrode fabrication studies have focused on insulation of the interior surface of the cuff electrodes. The use of PECVD dielectrics deposited at low substrate temperatures is currently being evaluated as an alternative to polymers as the insulation on the inside surface of the cuff. In order to expedite the animal studies, cuff electrodes fabricated from silicone sheet with wire electrodes are being obtained from Dr. James Sweeny. These nerve cuffs will have longitudinal tripoles located in each quadrant around the nerve.

2.1 Cuff Fabrication

The use of PECVD films of amorphous SiC:H have been described in related work (Thin Film Hermetic Coatings, NINDS Contract No. N44-NS-2-2311). Both a-SiC:H and a-SiOC:H, which has a higher electronic resistivity than a-SiC:H, have been deposited on FEP Teflon^R at a substrate temperature of 100°C. Preliminary evaluation of the coatings indicates that they are

adherent to the FEP substrate under dry conditions. Evaluation of the adhesion in saline soak tests at elevated temperatures is now underway. Both dielectrics are also adherent to metal substrates when deposited at 100°C. If the dielectrics are adherent to FEP Teflon^R during soak tests, they will be used alone or in conjunction with a silicone polymers as insulation. We anticipate the dielectric surface having a higher affinity for the silicones than the FEP Teflon^R and derivitization of the dielectrics to promote adhesion may be possible.

3 .0 *IN VIVO* STUDIES

Progress Report #2: Thin-Film Peripheral Nerve Electrode

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3.1 Abstract of *In Vivo* Studies

We have proposed that complex hand movements might be obtained with direct median nerve stimulation through an implanted multielectrode nerve cuff. We expect to show that selective stimulation of digits can induce a graded response. In addition, the direct nerve stimulation should induce repeatable hand responses and result in no injury to the nerve.

3.2 Progress on *In Vivo* Studies

In preparation for studies with new nerve cuff electrodes, it became apparent to us that we needed more experience with electromyographic (EMG) recording from the forearm muscles as well as experience with recording torque responses of different hand movements. Therefore, we requested and received authorization from our Institutional Animal Review Committee to conduct one-day studies in the raccoon under anesthesia. The studies used sterile percutaneous electrodes for stimulation and recording. Electrode wires were inserted with a small 27G needle. Four raccoons have been evaluated with this method on eight different days. The animals have recovered without adverse responses. The studies have been successful and we have established our stimulation and recording techniques.

The electromyographic recording protocols that show selective stimulation of muscles have been established. Bipolar stimulation and recording electrodes were inserted in the muscle pronator

teres. Recording the EMG to stimulation revealed a stimulation artifact and an "M" wave of approximately 40 μs duration. The EMG record was electronically modified to suppress the artifact and to record the full wave rectified voltage. This value was suitable for recording on a strip chart recorder as a measure of muscle contractile activity. Chart recordings from the pronator teres showed increasing responses to increasing stimulation currents, whereas, other muscles such as flexor digitorium superficialis did not exhibit an EMG during pronator teres stimulation. Further, "F" waves due to spinal reflexes were absent in our animal study. The lack of an "F" wave is probably due to the anesthesia.

A torque recording platform constructed in our model shop held the raccoon arm and allowed free digit movement. The paw was clamped to allow only a single movement such as wrist flexion, wrist pronation, or phalanges flexion. Torques were recorded in response to direct muscle stimulation with the percutaneous electrodes. Pronator teres stimulation resulted in pronation of the hand. Flexor digitorum profundus had a general response with hand pronation, flexion, and phalanges flexion. thus, torque measures are less specific for individual muscles than EMG recordings.

The sixteen channel, Clarion implantable stimulator has been received and is being evaluated. Maximum recruitment of forearm muscles to stimulation has been shown using the Clarion with long pulse durations (300 μs) and currents up to the maximum of 6 ma.

4. FUTURE WORK

The anticipated tasks for the next reporting period are as follows:

- evaluation of nerve cuffs in acute studies on the raccoon median nerve;
- evaluation of PECVD SiC:H and a-SiOC:H as dielectric insulation on FEP Teflon^{R} and sputter deposited metallization;
- evaluation of silicone polymers as inner surface insulation using as-deposited and derivitized PECVD SiC:H and a-SiOC:H as adhesion layers to FEP Teflon^{R}.